

510(k) Summary

1. Submitter: **MPS Acacia**
499 Nibus Street Suite E
Brea, CA 92821
Tel: 714-257-0470
Fax: 714-257-0513
2. Contact: Fergie F. Ferguson, RA/QA Manager
MPS Acacia
3. Date prepared: April 9, 2001
4. Device trade name: **MPS Acacia MedFlo LI Elastomeric Pump**
MPS Acacia MedFlo LI KVO Elastomeric Pump

Common name: **Elastomeric Infusion Pump**
5. Predicate device: **MedFlo® II Elastomeric Pump**
510(k) number: **K911636**
Marketed by: **MPS Acacia**
499 Nibus Street Suite E
Brea, CA 92821

Predicate device: **MPS Acacia Pain Kit**
510(k) number: **K003476**
Marketed by: **MPS Acacia**
499 Nibus Street Suite E
Brea, CA 92821

Predicate device: **Homepump C-Series and**
Homepump C-Series One-Step KVO
Elastomeric Pump
510(k) number: **K991513**
Marketed by: **I-Flow Corporation**
20202 Windrow Drive
Lake Forest, CA 92630
6. Description:

The MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps are infusion pumps with integrated administration sets. The elastomeric membrane functions as the fluid reservoir and the pressure source. The pressure that pumps the fluid comes from the strain energy of the elastomeric membrane which is forced to expand when the pump is filled. The incorporation of a set flow restrictor with a set elastomeric pressure produces the desired flow rate. Fill volumes of 100 to 300ml with flow rates of 0.5 to 10 ml/hr are available. The KVO model incorporates an optional Y-site and optional checkvalve at the distal end of the administration set.
7. Intended Use:

7.1 The MPS Acacia MedFlo LI Elastomeric Pump is intended for the continuous infusion of medications for general use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

7.2 The MPS Acacia MedFlo LI KVO Elastomeric Pump is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

7.3 The MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps are disposable and single use only.

8. Technological comparison to predicate device:

The MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps offer identical technique, usage parameters and intended use to the predicate devices. The elastomeric membrane delivers fluid at a controlled rate and manner the same as the predicate devices.

9. Non-clinical test summary:

All components used in the MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps are identical to the components used in the predicate device from MPS Acacia, 510(k) number K003476.

10. Conclusion:

The MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps are substantially equivalent to the products currently being legally marketed by MPS Acacia and I-Flow Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2001

Ms. Fergie F. Ferguson
RA/QA Manager
MPS Acacia
499 Nibus Street, Suite E
Brea, California 92821

Re: K011117
Trade/Device Name: MPS Acacia Medflo Infusion (LI) and
MedFlo LI KVO Elastomeric Pumps
Regulation Number: 880.5725
Regulatory Class: II
Product Code: MEB and FRN
Dated: April 9, 2001
Received: April 12, 2001

Dear Ms. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

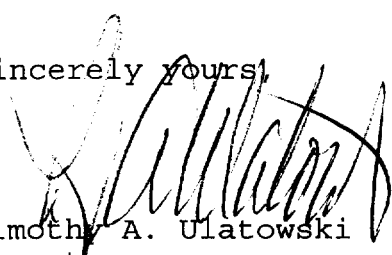
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K011117DEVICE NAME: MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps

INDICATIONS FOR USE:

1. The MPS Acacia MedFlo LI Elastomeric Pump is indicated for the continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
2. The MPS Acacia MedFlo LI KVO Elastomeric Pump is indicated for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.
3. The MPS Acacia MedFlo LI and MedFlo LI KVO Elastomeric Pumps are disposable and single use only.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)Prescription Use ✓
(Per 21 CFR 801.109)OR Over-The-Counter-Use _____
(Optional Format 1-2-96)*Patricia Cucchi*
(Division Sign-Off)Division of Dental, Infection Control,
and General Hospital Devices510(k) Number K011117